NDA 20-676/S-001
NDA 20-676/S-003

Bristol Myers Squibb
Attention: Mr. Allen Skupp
Director, Global Regulatory Affairs
1350 Liberty Avenue
Hillside, New Jersey 07205

24 APR 2001

Dear Mr. Skupp:

Please refer to your supplemental new drug applications dated September 18, 1997 and May 1, 2000, received September 22, 1997 and May 5, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vagistat® Vaginal Ointment.

We acknowledge receipt of your submissions dated March 21, 2001.

These supplemental new drug applications provide for the treatment of vaginal yeast infections.

We have completed the review of these supplemental applications, SLR-001 that has been superceded by SLR-003 as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text and with the minor editorial revisions listed below. Accordingly, these supplemental applications are approved effective on the date of this letter.

1. The labeling specifications are acceptable, with the exception of the six point bullet size. The regulations of 21 CFR 201.66 9d) specify that bullet size must be 5 point.

2. In the tamper-evident statement on the back panel of the carton and on the front of the pouch, replace the word “broken” with “open” for readability and consistency with other OTC drug product labeling.

3. On the front of the pouch, under the trade name “Vagistat-1,”revise the SOI to read
   Tioconazole Ointment 6.5%
   Vaginal Antifungal

4. In the Questions and Comments section, the telephone number reference (1-888-Vagistat) needs to be modified. The product name should not be in the Drug Facts box.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted draft labeling (immediate container and carton labels) submitted March 21, 2001 and must be formatted in accordance with the requirements of 21 CFR 201.66. These revisions are terms of the approval of these applications.

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 20-676/ S-003." Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Daniel P. Keravich, M.S., M.B.A., Regulatory Health Project Manager, at 301-827-2248.

Sincerely,

Linda M. Katz, M.D., M.P.H.
Deputy Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research